December 15, 2022

Polymedics Innovations GmbH
Kenneth K. Kleinhenz
Regulatory Affairs
Heerweg 15D
Denkendorf, D-73770
Germany

Re: K090160
Trade/Device Name: Suprathel Wound and Burn Dressing
Regulatory Class: Unclassified
Product Code: QSZ

Dear Kenneth K. Kleinhenz:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 20, 2009. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSZ.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 2009

PolyMedics Innovations GmbH
% Mr. Kenneth K. Kleinhenz
Regulatory Affairs
Heerweg 15D, 73770 Denkendorf
Germany

Re: K090160
Trade/Device Name: Suprathel Wound and Burn Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 7, 2009
Received: May 11, 2009

Dear Mr. Kleinhenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

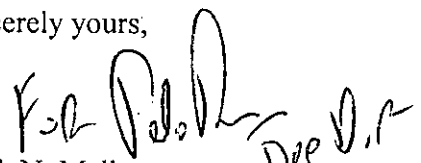
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

(240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Device Name: **Suprathel Wound and Burn Dressing** K090160

Indications for Use:

The Suprathel Wound and Burn Dressing is indicated for temporary coverage of non-infected skin defects, such as superficial wounds, under sterile conditions. The dressing is intended to maintain a moist wound healing environment. A moist wound healing environment allows autolytic debridement.

The Suprathel Wound and Burn Dressing is used in the management of:

- Partial and full thickness wounds
- Pressure (stage I and IV) and venous ulcers
- Ulcers caused by mixed vascular etiologies
- Venous stasis and diabetic ulcers
- 1st and 2nd degree burns
- Partial thickness burns
- Cuts and abrasions
- Acute wounds
- Trauma wounds
- Surgical wounds
- Superficial wounds
- Grafted wounds and donor sites

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krone for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090160

K090160

MAY 20 2009

ADMINISTRATIVE INFORMATION

Manufacturer Name:	PolyMedics Innovations, GmbH Heerweg 15D Denkendorf, Germany D-73770
Official Contact:	Kenneth K. Kleinhenz Regulatory Affairs Telephone (858) 458-0900 Fax (858) 458-0994

DEVICE NAME

Classification Name:	Dressing, Wound and Drug
Trade/Proprietary Name:	Suprathel Wound and Burn Dressing

ESTABLISHMENT REGISTRATION NUMBER

This is our first device applications to FDA. We will register and pay the fee within 30 days of FDA's approval/clearance of this device.

DEVICE CLASSIFICATION AND PRODUCT CODE

Wound and Drug Dressings are unclassified and have been assigned Product Code FRO.

INTENDED USE

The Suprathel Wound and Burn Dressing is indicated for temporary coverage of non-infected skin defects, such as superficial wounds, under sterile conditions. The dressing is intended to maintain a moist wound healing environment. A moist wound healing environment allows autolytic debridement.

The Suprathel Wound and Burn Dressing is used in the management of:

- Partial and full thickness wounds
- Pressure (stage I and IV) and venous ulcers
- Ulcers caused by mixed vascular etiologies
- Venous stasis and diabetic ulcers
- 1st and 2nd degree burns
- Partial thickness burns
- Cuts and abrasions
- Acute wounds
- Trauma wounds
- Surgical wounds
- Superficial wounds
- Grafted wounds and donor sites

DEVICE DESCRIPTION

The Suprathel Wound and Burn Dressing is a tri-polymer, bioresorbable dermal covering that is provided in a flat sheet. The Suprathel Wound and Burn Dressing can be cut with scissors to the desired shape and size. The Suprathel Wound and Burn Dressing is fully malleable at room temperature and becomes more pliable at body temperature and thus can be conformed three dimensionally to most any anatomical orientation. The Suprathel Wound and Burn Dressing can be used either alone or in conjunction with various conventional gauze dressings with and without fatty additives, which can also serve to further secure the Suprathel Wound and Burn Dressing and prevent dislocation.

The PolyMedics Innovations (PMI) Suprathel Wound and Burn Dressing is provided in various shapes such as rectangles, ovals, and circles and will be provided in other shapes and sizes as needed for particular wound and burn-care applications. The PolyMedics Innovations (PMI) Suprathel Wound and Burn Dressing is provided in sheets of 50mm x 50mm to 180mm to 230mm and will be provided in other shapes and sizes as needed for particular burn and wound-care applications. The thickness of the PolyMedics Innovations (PMI) Suprathel Wound and Burn Dressing ranges from 50μm to 200μm according to the region to be treated. The PolyMedics Innovations (PMI) Suprathel Wound and Burn Dressing is provided in solid sheets that contain micropores that range in size from 2μm to 50μ.

Material Composition

The Suprathel Wound and Burn Dressing is frabricated from a tri-polymer of polylactide, trimethylene carbonate, and ε-caprolactone.

In Vitro Testing

Mechanical testing was performed on the PolyMedics Innovations (PMI) Suprathel Wound and Burn Dressing which determined the PolyMedics Innovations (PMI) Suprathel Wound and Burn Dressing to be substantially equivalent to the mechanical strengths of the predicate devices under indication for use conditions.

CLINICAL EVIDENCE

Human clinical experience demonstrated that the PolyMedics Innovations (PMI) Suprathel Wound and Burn Dressing is safe and efficacious for the indications for use.

EQUIVALENCE TO MARKETED PRODUCT

The PolyMedics Innovations (PMI) Suprathel Wound and Burn Dressing shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: BioCore Medical Collatek Sheet (K012995), Biomet Merck Topkin Foil (K031684), Inion OTPS Biodegradable Pin (K031712), MacroPore Surgi-Wrap MAST Bioresorbable Sheet (K031955), Nymed Group Hydrolyzed Collagen Gel with Silver (K061227), Biomet Mesofol (K062558), BioDerm BTF Thin Film Wound Dressing (K982939), and Integra Life Sciences HeliDerm (K990086); Class II medical devices that were cleared for marketing in the United States under K012995, K031684, K031712, K031955, , K061227, K062558, K982939, and K990086 respectively.

Indications for Use

The Suprathel Wound and Burn Dressing shares indications for use principles with the predicate devices as they are indicated for uses as temporary dermal coverings of non-infected skin defects and various dermal wounds.

Design and Materials

The design of the PolyMedics Innovations (PMI) Suprathel Wound and Burn Dressing and the predicate devices Biomet Merck Topkin Foil (K031684), Integra Life Sciences HeliDerm (K990086), Nymed Group Hydrolyzed Collagen Gel with Silver (K061227), and BioCore Medical Collatek Sheet (K012995), BioDerm BTF Thin Film Wound Dressing (K982939) are substantially equivalent as they are all sterile, single use, thin, flat, rectangular sheets with design charactersitics of being flexible and semi-rigid devices that can be contoured in situ and cut to shape with surgical scissors. Furthermore, the PolyMedics Innovations (PMI) Suprathel Wound and Burn Dressing and the predicate devices Biomet Merck Topkin Foil (K031684), Integra Life Sciences HeliDerm (K990086), Nymed Group Hydrolyzed Collagen Gel with Silver (K061227), and BioCore Medical Collatek Sheet (K012995) are substantially equivalent as they all share the characteristics of being semi-rigid flat sheets fabricated from a bioresorbable material. Additionally, the PolyMedics Innovations (PMI) Suprathel Wound and Burn Dressing and the Biomet Merck Topkin Foil (K031684) predicated device share more design features as they are fabricated from substantially equivalent bioresorbable polymers and they both contain micropores that range from 2 to 50 microns in size. The Merck Topkin Foil (K031684) predicated device also shares design features of thickness with the PolyMedics Innovations (PMI) Suprathel Wound and Burn Dressing as the Merck Topkin Foil ranges in thickness from 70 to 130 microns while the Suprathel device has a substantially equivalent thickness of 50 to 200 microns.